

## **REMARKS**

This paper is prepared in response to the Office Action dated August 20, 2008. Currently, claims 1-12, 21, 22 and 24-34 are pending in the application, wherein claims 1-12, 21, 22 and 24-34 have been rejected. Claims 1, 3, 4, 7-9, 21 and 22 have been amended, and claims 35-37 have been added with this paper. Support for the amendments may be found in the description and drawings as originally filed. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

### **Claim Objections**

Claims 1 and 3 are objected to for apparent informalities identified in the Office Action. Namely, the Examiner suggests that the first positive recitations of "the final medical device" lack antecedent basis, and may render the claims indefinite. Claims 1 and 3 have been amended with this paper to obviate this rejection. Withdrawal of the objection is respectfully requested.

### **Claim Rejections**

Claims 1-12, 21, 22 and 24-34 stand rejected under 35 U.S.C. §102(e) as being anticipated by Sharrow, U.S. Pat. Pub. No. 2004/0167438. Applicants respectfully traverse this rejection.

#### **Independent Claims 1 and 3**

Claims 1 and 3 each recite a method of manufacturing a medical device in which a core member has a proximal region, a distal region and a tapered region between the proximal region and the distal region. A polymer jacket is disposed over the distal region of the core member. A coil is wound over the polymer jacket distal of the tapered region. The medical device, in a final manufactured form, includes an outermost surface having a helical ridge extending around a circumference of the outermost surface formed at least in part by a length of the coil wound over the polymer jacket distal of the tapered region.

Sharrow fails to teach each limitation of these claims, necessary to anticipate either claim 1 or claim 3. In formulating the rejection, it appears as though the Examiner is relying on the portion of Sharrow disclosing an exposed braid portion 412a which "may enhance the ability of a clinician to effectively grasp and actuate device 410." Sharrow at paragraph 0046. Thus, this

exposed braid portion 412a is in a proximal portion of the device which remains exterior of a patient during a medical procedure such that the clinician can more easily manipulate the device 410 with his/her hands. This exposed braid portion 412a is not located distal of a tapered region in the distal region of the device as currently claimed.

For at least these reasons, Sharrow does not anticipate either claim 1 or claim 3. Claims 2, 6 and 24, which depend from one of claims 1 and 3 and which include additional limitations, are also believed allowable over the teachings of Sharrow for at least the reasons stated above. Withdrawal of the rejection is respectfully requested.

Independent Claim 4

Claim 4 recites that the coil includes a central metallic core material and an outer coating surrounding the central metallic core material. At no point does Sharrow disclose a coil including a central metallic core material and an outer coating surrounding the central metallic core material.

Before discussing the merits of the rejection of claim 4, it is noted that to anticipate a claim under the provisions of 35 U.S.C. §102(e), the reference must teach every element of the claim. See M.P.E.P. §2131. “The identical invention must be shown in as complete detail as is contained in the...claim.” M.P.E.P. §2131, citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). Claim 4 expressly recites that “the coil includes a central metallic core material and an outer coating surrounding the central metallic core material.”

In attempting to identify the portion of Sharrow relied on as teaching a central metallic core material and an outer coating surround the central metallic core material, specific reference was made to paragraphs 35, 36 and 39 of Sharrow, as well as paragraphs 29-31, 38 and 56 of Zhou, which was incorporated by reference in the description of Sharrow. Applicants respectfully assert these paragraphs of Sharrow, including the paragraphs of Zhou, fail to teach the identical invention as recited in claim 4, including the recited detail of a coil including a central metallic core material and an outer coating surrounding the central metallic core material as currently claimed.

Paragraph 35 of Sharrow indicates that the strands or filaments of the braid “may be appropriately sized and shaped”, giving some possible cross-sectional shapes of the filaments.

There is no discussion directed to a central metallic core material or a coating surrounding a core material.

Paragraph 36 of Sharrow states that the reinforcing member, for example a coil, “may be made of a variety of materials including metals, metal alloys, polymers, and the like”, listing several possible materials of the coil. At no point in this paragraph is it expressly taught that the coil of Sharrow includes a central metallic core material and an outer coating surrounding the central metallic core material with the detail required to anticipate claim 4.

Paragraph 39 of Sharrow recites:

In addition to or as an alternative to being spaced from core wire 14, braid 12 may also improve torque transmission based on its material composition and configuration. For example, braid 12 may be comprised of a strong or high modulus material such as aramid (also known as poly-para-phenylene terephthalamide such as, for example, KEVLAR®, which is commercially available from DuPont). Alternatively, braid 12 or the filaments making up the braid may be made of other materials such as polymers, metals, metal alloys, or combinations thereof, for example like those materials disclosed above with reference to materials useable for the core wire 14. For example, braid 12 may include a first filament made from a combination of materials, or braid 12 may include a first filament made of a first material and a second filament made from a second material. In some embodiments, the material of braid 12 can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 5% LCP. This has been found to enhance torqueability. In some other embodiments, braid 12 can include combinations of filaments or strands made up of different types of materials. Also, braid 12 can include radiopaque materials or materials that are MRI compatible as discussed above.

This paragraph of Sharrow teaches additional material compositions and configurations of the braid 12. For example, this paragraph states that the braid “may be comprised of a strong or high modulus material such as aramid.” Additionally, this paragraph states that “the material of the braid 12 can be blended with a liquid crystal polymer (LCP)” and the braid “can include radiopaque materials or materials that are MRI compatible.”

Furthermore, this paragraph states that the “braid 12 can include combinations of filaments or strands made up of different types of materials” teaching that “braid 12 may include a first filament made from a combination of materials, or braid 12 may include a first filament made of a first material and a second filament made from a second material.” A generic

discussion that the filaments may be made from a combination of materials is insufficient to anticipate the detailed recitation of claim 4.

Applicants respectfully assert that, in the event the Examiner is relying on these teachings of Sharrow, these passages are insufficient to describe in as complete detail as found in claim 4, a coil including a central metallic core material and an outer coating surrounding the central metallic core material as currently claimed.

Turning now to the paragraphs of Zhou referred to in the rejection. Paragraph 29 of Zhou indicates that the reinforcing member “can be formed using any suitable technique”, stating that “the braid can be formed using a suitable number of strands or filaments” and that the strands or filaments of the braid “should be appropriately sized and shaped”, giving some possible cross-sectional shapes of the filaments. There is no discussion directed to a central metallic core material or a coating surrounding a core material.

Paragraph 30 of Zhou states:

Reinforcement layer **32** may include strands or fibers of any suitable material. Some examples of suitable materials can include, for example, polymers, metal-polymer composites, metals, metal alloys, or the like, or combinations or mixtures thereof. At least a portion of the reinforcing member **32**, or at least some of the filaments or strands making up the reinforcing member **32**, can be made of a metallic material, polymeric material, or combinations thereof. In some embodiments or application, suitable metallic materials include, for example, those that can be annealed into a desired shape. Some examples of metallic materials include stainless steel, tungsten, nickel, cobalt, titanium, gold, iridium, or alloys thereof including, for example, nickel-titanium alloy, such as linear elastic or superelastic nitinol, nickel-chromium alloy, nickel-chromium-iron alloy, as well as other such metallic materials, or combinations thereof. Some particular examples of suitable stainless steel alloys include especially high tensile grades, and/or other grades such as **304** and **440A** and **440C** stainless steel alloys, as well as alloys containing titanium. In some example embodiments, the reinforcing member is a reinforcing braid adapted and configured for use in an intravascular catheter and is formed with primarily stainless steel filaments. For additional embodiments, suitable polymeric materials also include those that can be annealed into a desired shape. Some examples of suitable polymers include nylon, polyesters, acrylics and combinations of mixtures thereof. The strands may also comprise non-metal materials such as liquid crystal polymer (LCP) fibers, glass fibers, etc.

Thus, this paragraph of Zhou teaches numerous materials of which the strands or fibers of the reinforcement layer **32** may be made of. However, throughout this paragraph there is no

express teaching of a coil including a central metallic core material and an outer coating surrounding the central metallic core material as currently claimed, necessary to anticipate claim 4.

Paragraph 31 of Zhou states:

In some embodiments, the reinforcing member 32 includes combinations of filaments or strands made up of different types of materials. For example, in some particular example embodiments, the reinforcing member 32 is a reinforcing braid formed with a combination of stainless steel filaments and tungsten filaments.

Applicants respectfully assert that, in the event the Examiner is relying of these teachings of Zhou, these passages do not describe in detail a coil including a central metallic core material and an outer coating surrounding the central metallic core material as currently claimed.

Paragraph 38 of Zhou teaches that the braid structure may be of various configurations, such as “unbalanced braiding”, “strands of different shapes and weights”, “strands of different compositions” and “uneven weaving patterns.” There is no discussion directed to a central metallic core material or a coating surrounding a core material.

Paragraph 56 of Zhou teaches that “combinations of wires and sizes can also be used” suggesting wires of one material may be mixed with wires of another material and/or wires of a first size may be mixed with wires of another size. There is no discussion directed to a central metallic core material or a coating surrounding a core material.

Applicants respectfully assert that at no point throughout Sharrow, including the description of Zhou, is the identical invention of claim 4 taught in as complete detail as is contained in claim 4. For at least these reasons, Sharrow does not anticipate claim 4. Claims 5 and 25, which depend from claim 4 and which include additional limitations, are also believed allowable over the teachings of Sharrow for at least the reasons stated above. Withdrawal of the rejection is respectfully requested.

Independent Claims 7, 8, 9, 21 and 22

Claims 7, 8, 9, 21 and 22 each recite a method of manufacturing a guidewire in which a core member has a proximal region, a distal region and a tapered region between the proximal region and the distal region. A jacket is disposed over the distal region of the core member. A coil is disposed over the jacket distal of the tapered region. The guidewire, in a final

manufactured form, includes an outermost surface having a helical ridge extending around a circumference of the outermost surface formed at least in part by a length of the coil disposed over the jacket distal of the tapered region.

Sharrow fails to teach each limitation of these claims, necessary to anticipate these claims. In formulating the rejection, the Examiner is relying on the portion of Sharrow disclosing an exposed braid portion 412a which “may enhance the ability of a clinician to effectively grasp and actuate device 410.” Sharrow at paragraph 0046. As discussed above, this exposed braid portion 412a is in a proximal portion of the device which remains exterior of a patient during a medical procedure such that the clinician can more easily manipulate the device 410 with his/her hands. This exposed braid portion 412a is not located distal of a tapered region in the distal region of the device as currently claimed.

For at least these reasons, Sharrow does not anticipate any of claims 7, 8, 9, 21 and 22. Claims 10-12 and 26-34, which depend from one of claims 7, 8, 9, 21 and 22 and which include additional limitations, are also believed allowable over the teachings of Sharrow for at least the reasons stated above. Withdrawal of the rejection is respectfully requested.

#### **Newly Added Claims**

Newly added claims 35-37, which depend from claims 1, 7 and 21, respectively, are believed allowable over the teachings of Sharrow for at least the reasons stated above. Favorable consideration of these claims is respectfully requested.

**Conclusion**

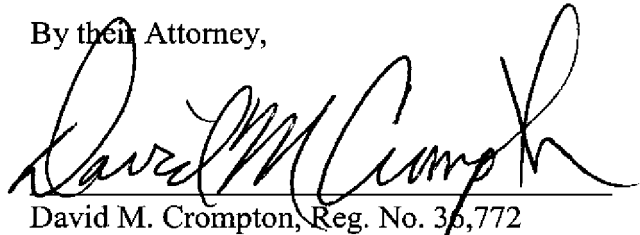
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Brian R. Reynolds et al.

By their Attorney,

Date: 11/20/08

A handwritten signature in black ink, appearing to read "David M. Crompton", written over a horizontal line.

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